

**Docket No.: TORY-0002 (31532-2003)
PATENT**

**Serial Number: 09/257,902
Filed: February 25, 1999**

63. An article of manufacture of claim 59, wherein the iron granules are no more than about 850 microns in diameter.

64. An article of manufacture of claim 59, wherein the iron granules are encapsulated with a coating, said coating being prepared from a compound selected from the group consisting of monoglycerides, diglycerides, ethyl cellulose, hydrogenated soy bean oil and mixtures thereof.

65. An article of manufacture of claim 59, wherein the iron granules are encapsulated with a coating selected from the group consisting of monoglycerides, diglycerides, ethyl cellulose, hydrogenated soy bean oil and mixtures thereof; and the excipient is an edible oil in hydrogenated form.

66. An article of manufacture of claim 59, wherein the composition contains one or more of a bioavailable form of an additional micronutrient.

67. An article of manufacture of claim 59, wherein the composition contains one or more of a bioavailable form of a compound selected from zinc, vitamin A, iodine and ascorbic acid.

REMARKS

Status of the Claims

Claims 7-30 and 32-35 are in the application.

Claims 7-30 and 32-35 have been rejected.

By way of this amendment, claims 7-30 and 32-35 have been canceled and new claims 36-67 have been added.

Docket No.: TORY-0002 (31532-2003)
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Summary of the Amendment

New claims 36-67 have been amended to more clearly define the instant invention. Support for the amendments to claims 36-67 can be found throughout the specification and claims as originally. No new matter has been added.

New claims 36-50 relate to methods of preventing iron deficiency anemia in a mammal. New claims 36 and 43 specifically recite that the "food and micro-encapsulated iron granules" are administered to the mammal and that "the mammal consumes a therapeutically effective amount of iron as micro-encapsulated iron granules." Each of the claims contains this limitation. Additionally, new claims 43-50 include the limitation that the contents of the packaging material are "a composition that consists essentially of an admixture of a single daily dose of a therapeutically effective amount of elemental iron as microencapsulated iron granules in combination with an excipient, and optionally, one or more of a bioavailable form of an additional micronutrient;" Thus, claims 43-50 include the further limitation that the composition is provided in and removed from a packaging material that contains a single daily dose of iron.

New claims 51-67 refer to articles of manufacture which comprise an iron containing composition in a packaging material. New claims 51 and 59 specifically recites that the article of manufacture consists essentially of the packaging material and the composition therein. Furthermore, new claims 51 and 59 specifically recites that the composition consists essentially of micro-encapsulated iron, a lipid-based excipient and optionally additional micronutrients. Each of claims contains each of these limitations. Additionally, new claims 59-67 include the limitation that the contents of the packaging material are "a composition that consists essentially of an admixture of a single daily dose of a therapeutically effective amount of elemental iron as microencapsulated iron granules in combination with an excipient, and optionally, one or more of a bioavailable form of an additional micronutrient;" Thus, claims 59-67 include the further limitation that the article of manufacture contains a single daily dose of iron.

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Rejection under 35 U.S.C. 103(a)

Claims 7-30 and 32-35 stand rejected under 35 U.S.C. 103(a) as obvious in view of Kovacs et al. Page 2 of the Official Action includes a specific reference to column 2, lines 17-65 of Kovacs that discloses bead like forms of iron dispersed in a solid fat carrier and subsequently added to food. Claims 7-30 and 32-35 are canceled and the rejection is moot. Applicant respectfully urges that Kovacs neither teaches nor suggests the invention as set forth in new claims 36-66.

With respect to method claims 36-50, Kovacs does not teach or suggest the claimed invention. Kovacs teaches mixing elemental iron with a fat carrier and generating a powder like form of the mixture which can be sprinkled in food during the manufacturing process. Kovacs teaches that the food is hot such that the mixture binds to the food being manufactured by melting the fat. Kovacs does not teach administering the iron to a mammal such that the mammal consumes a therapeutically effective amount of iron as micro-encapsulated iron granules. Kovacs does not teach that the mammal consumes micro-encapsulated iron. Rather Kovacs teaches that the fat component of the iron/fat mixture melts in order to adhere the iron to the food. The addition of the iron/fat mixture to hot food during the manufacturing process precludes the presence of therapeutically effective amount of iron as micro-encapsulated iron granules. Because Kovacs teaches adding the supplement during the manufacturing process, the iron is bound to the food through the melting of the fat carrier.

The claimed invention provides a composition that is added to food and administered by consumers at the time meals are prepared such that the micro-encapsulated iron is administered to the mammal and consumed thereby. According to the invention, the mammal consumes a therapeutically effective amount of iron as micro-encapsulated iron granules. Kovacs neither teaches nor suggests that a therapeutically effective amount of iron can be administered as micro-encapsulated iron granules. Kovacs neither teaches nor suggests the methods claimed in new claims 36-50.

New claims 43-50 further contain the additional limitation that the packaging material contains a single dose of elemental iron. Kovacs is specifically directed to methods in which the supplemental iron is added during manufacturing and does not

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teach and suggest adding supplemental iron from a package containing a single daily dose. Rather, Kovacs teaches away from adding supplemental iron from a package containing a single daily dose. Kovacs does not render new claims 43-50 obvious.

With respect to claims 51-67, these claims are directed to an article of manufacture and specifically recite that the article of manufacture consists essentially of the packaging material and the composition; and that the composition consists essentially of the micro-encapsulated iron, the lipid excipient and optional micronutrients. Kovacs neither teaches nor suggests an article of manufacture as defined by new claims 51-67.

Kovacs does not describe or suggest article of manufacture that consists essentially of the packaging material and the composition. As discussed above, because Kovacs is specifically and exclusively relevant to a food manufacturing process, Kovacs has no motivation to produce a packaged microencapsulated iron product. Furthermore, because Kovacs is specifically and exclusively relevant to a food manufacturing process, nothing in Kovacs would motivate someone skilled in the art to produce an article of manufacture that consists essentially of the composition in a packaging material. Likewise, one skilled in the art would not be motivated to produced a packaged composition with a package that includes labeling as set forth in the claims. Accordingly, Kovacs neither teaches nor suggests the invention claims in new claims 51-67.

New claims 59-67 further contain the additional limitation that the packaging material contains a single dose of elemental iron. Kovacs is specifically directed to methods in which the supplemental iron is added during manufacturing and does not teach and suggest an article of manufacture having a package containing a single daily dose of supplemental iron. Kovacs is specifically and exclusively relevant to a food manufacturing process, nothing in Kovacs would motivate someone skilled in the art to produce an article of manufacture that consists essentially of the composition in a packaging material in a single daily dose. Rather, Kovacs teaches away from an article of manufacture having a package containing a single daily dose of supplemental iron. Kovacs does not render new claims 59-67 obvious.

Docket No.: TORY-0002 (31532-2003)
PATENT

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Conclusion

For the foregoing reasons, claims 36-67 are in condition for allowance. The examination of these claims and passage to allowance are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicant invites the Examiner to contact the undersigned at (215) 665-5592 to clarify any unresolved issues raised by this response.

Attached hereto is a marked-up version of the changes made to the application by the current amendment. The attached page is captioned "Version with markings to show changes made."

Respectfully submitted,



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**Docket No.: TORY-0002 (31532-2003)
PATENT**

**Serial Number: 09/257,902
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 7-30 and 32-35 have been canceled and claims 36-67 have been added.